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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

RICHARD CONNELLY, **Plaintiff,** **v.** **ST. JUDE MEDICAL, INC., a Minnesota corporation; ABBOTT LABORATORIES AS THE SUCCESSOR IN INTEREST TO ST. JUDE MEDICAL, INC., an Illinois corporation; and PACESETTER, INC., dba St. Jude Cardiac Rhythm Management Division, a Delaware corporation,** **Defendants.**	**Case No.** **COMPLAINT FOR:** **1. STRICT LIABILITY — MANUFACTURING DEFECT;** **2. STRICT LIABILITY — FAILURE TO WARN;** **3. NEGLIGENCE PER SE; and** **4. NEGLIGENCE.** **DEMAND FOR JURY TRIAL**

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I. INTRODUCTION

1. An implantable cardioverter defibrillator monitors a patient's heart rate through thin wire leads connected to the heart. When an abnormal heart rate is detected, the defibrillator delivers an electric shock through the leads to the heart to restore a normal heartbeat. This case is about the damage done by materially defective St. Jude Riata Leads, known by the manufacturers to fire improperly, sending repeated, violent shocks to the heart that could kill or permanently damage the unsuspecting patient. Because Defendants failed to disclose the known defects with these eroding leads, Plaintiff Richard Connelly faced catastrophic risk, finally suffering sudden, repeated, erroneous shocks to his heart, resulting in excruciating pain, heart trauma, and a near death experience. Through this case, Richard Connelly seeks to hold Defendants responsible for the life-threatening damages he suffered and continues to suffer.

2. Plaintiff Richard Connelly brings this action against Defendants St. Jude Medical, Inc., Abbott Laboratories as the successor in interest to St. Jude Medical, Inc., and Pacesetter, Inc., dba St. Jude Cardiac Rhythm Management Division (collectively "St. Jude" or "Defendants"), for injuries caused by manufacturing defects in the St. Jude Riata and/or Riata ST Leads ("Riata Leads"). Riata Leads are wires manufactured by Defendants to connect St. Jude defibrillators to a patient's heart.

3. In **2003**, **2007**, and **2015**, respectively, Mr. Connelly had St. Jude defibrillators surgically installed and connected to his heart using the defective Riata Leads. Despite knowing for over a decade that the Riata Leads were materially defective – ***posing the risk of catastrophic harm or death*** – St. Jude never advised Mr. Connelly of the product defect and never advised Mr. Connelly or, on information and belief, his doctors or the U.S. Food & Drug Administration ("FDA") that, given Mr. Connelly's age and overall health *before* the Riata Leads caused irreparable damage, the defective Riata Leads should have been immediately replaced when Defendants discovered the Riata Leads were materially defective. Because Defendants were so tardy in disclosing the material defects in the Riata Leads, experts are only now beginning to understand the best ways to ameliorate the harm posed by installed Riata Leads.

4. The only basis for this flagrant failure to warn is corporate greed; Defendants put boosting the St. Jude stock price and bolstering the coffers of executives and board members above patient safety. ***Given the cost of replacing all defective Riata Leads in patients like Mr. Connelly, Defendants chose earnings over patient safety, even though Defendants knew there was a real risk of catastrophic damage and death to patients with St. Jude Riata Leads, including Mr. Connelly.*** As a direct result of product defects in the Riata Leads and Defendants' failure to take appropriate and timely responsibility for these product defects, thousands of patients were unwittingly forced to play a daily game of Russian roulette: would the St. Jude Riata Leads function properly or would they fire improperly, sending repeated, violent shocks to the heart that could kill or permanently damage the unsuspecting patient.

5. In **November 2016**, Mr. Connelly became one of the latest victims of St. Jude's malfeasance. His Riata Leads malfunctioned, ***improperly shocking him sixteen to twenty times*** and causing irreparable harm to Mr. Connelly.

6. Implantable cardioverter defibrillators ("ICDs") are electronic, battery-powered devices used to monitor a patient's heart rate. The device is placed just below the skin in the chest or abdomen, and thin wires connect the ICD to the heart. These connecting wires are called leads. Once the leads are attached to the ICD, they are inserted through a major vein and attached directly to the muscle on the inside of the heart, thereby connecting the ICD to the heart. Electrodes that sense the heart's rhythm are built into the lead wires and positioned in the heart, where they monitor the heartbeat and correct any irregular rhythms. When an abnormal heart rate is detected, the defibrillator delivers an electric shock through the leads to the heart to restore a normal heartbeat if a patient's heart is beating too rapidly. Newer-model ICDs sometimes function as a pacemaker as well and can stimulate the heart if the heart rate is too slow. By way of example, below is an image of an ICD which was surgically implanted in Plaintiff Richard Connelly:

/ / /

/ / /

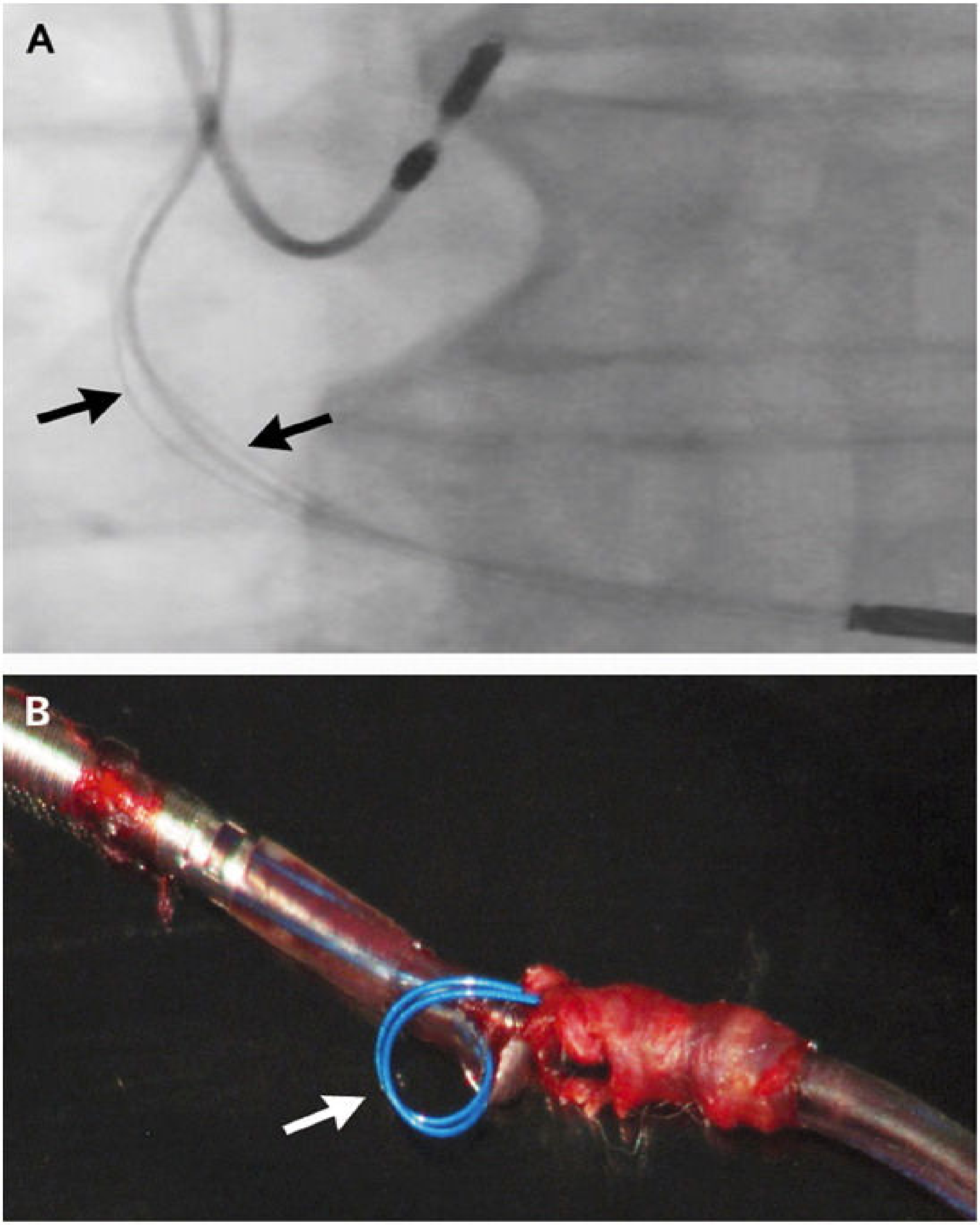
/ / /

(DF−1) SVC
OR PLUG
A (IS−1 BI)
SENSE/PACE
OR PLUG
(DF−1) RV
V (IS−1 BI)
SENSE/PACE

7. In or around **1996**, St. Jude received approval to market the predecessor of the Riata Leads. In or around 2002, St. Jude ultimately introduced its Riata Leads into the U.S. market. These St. Jude Riata Leads were based on the original 1996 submission and numerous supplements. The St. Jude Riata Leads had layers of insulation to protect electrical conductor wires inside the lead.

8. No later than **2005** and likely sooner, Defendants realized the Riata Leads were defective. The silicone coating insulating the electrical conductor wires within the leads was found to erode prematurely, posing catastrophic risk to patients who had the Riata Leads installed. Defective Riata Leads could trigger inaccurate and repeated shocks to the heart, causing excruciating pain, heart trauma, fear of imminent death, and death. Whereas Defendants began to face reports of safety problems with the Riata Leads at least as early as 2005, they did not notify

patients, physicians, or the FDA for years. What is more, a number of doctors notified Defendants about Riata Lead malfunctions, only to be rebuffed that the problems reflected "isolated events." Defendants knew these were not "isolated events" when they made these deceptive statements. Below is a depiction of Riata Leads with externalized conductors:



9. On **November 28, 2011**, Defendants were forced to recall the Riata Leads due to premature erosion of the insulation around the electrical conductor wires, known as insulation failure. Riata Lead malfunctions caused abnormal sensing or pacing, or delivery of inappropriate or no shock therapy, which resulted in serious adverse events, including violent shocks and death.

10. As of **2011**, whereas Defendants stopped selling Riata Leads, more than ***227,000*** Riata Leads had been distributed worldwide and approximately ***79,000*** Riata Leads remained implanted in patients in the United States, including in Plaintiff Richard Connelly.

11. In **2003**, **2007**, and **2015**, respectively, Mr. Connelly was implanted with three St. Jude ICDs, each of which connected to his heart with the same defective Riata Leads. Since 2003, Mr. Connelly met with representatives from Defendants every year in Monterey or Salinas, California to monitor his St. Jude ICDs and Riata Leads.

a. ***Despite knowledge that the Riata Leads were defective, at no time did the St. Jude representative inform Mr. Connelly that there had been any problems with either the St. Jude ICDs or the Riata Leads***.

b. ***Despite knowledge the defective Riata Leads could seriously injure or kill Mr. Connelly, at no time did the St. Jude representative advise Mr. Connelly, his doctors, or the FDA that he could or should remove or replace the St. Jude Riata Leads at Defendants' expense.***

12. Even though early extraction and replacement of at least one of the defective Riata Leads installed in Mr. Connelly was the surest way to safeguard Mr. Connelly's health, due to the monetary costs of extraction and replacement, Defendants never recommended that Mr. Connelly undergo the procedure.

13. On **November 13, 2016** at his home in Carmel, California, between five and six in the morning, Mr. Connelly was violently awakened when the St. Jude ICD and/or Riata Lead malfunctioned and shocked Mr. Connelly. Mr. Connelly struggled to get out of bed to reach the telephone to call 911. Mr. Connelly was terrified that he was having a deadly heart attack and believed he was dying. The intensity of the shocks, ***which numbered sixteen to twenty***, were so powerful, Mr. Connelly doubled over and was ultimately knocked to the ground.

14. Mr. Connelly was rushed to the Community Hospital of Monterey Peninsula in Monterey, California. Within fifteen to twenty minutes of Mr. Connelly's arrival at the hospital, a St. Jude representative, who lived only a few blocks away, arrived and used St. Jude machinery to turn off Mr. Connelly's St. Jude ICD and deactivate the Riata Leads. While Mr. Connelly was still in anguish, the St. Jude representative quipped: "it looks like you hit the lottery on this one."

15. On **March 2, 2017**, in Palo Alto, California, based on the advice of his cardiologist, Mr. Connelly underwent surgery at the Veterans Affairs (VA) Hospital to install a fourth St. Jude ICD and to replace one of the defective Riata Leads.

16. As a direct result of the defective and malfunctioning St. Jude ICD and/or Riata Leads, as well as Defendants' intentional and malicious choice to conceal and then downplay the defect, Mr. Connelly suffered incredible physical pain and continues to suffer mental and physical anguish. In addition, Mr. Connelly was forced to miss work and spend money on medical costs arising from St. Jude's defective ICD and/or Riata Leads. This lawsuit follows.

II. PARTIES

A. PLAINTIFF

17. Plaintiff Richard Connelly was born on **March 30, 1958**. After serving in the United States Marine Corps., Mr. Connelly settled in Carmel, California, where he works as a Produce Buyer. Since installation of his first St. Jude ICD and Riata Leads in **November 2003**, Mr. Connelly has had all of his medical appointments related to his heart in Monterey or Santa Clara Counties in Northern California. At most, if not every appointment, including **November 13, 2016** at the Community Hospital of Monterey Peninsula for treatment for shocks from the St. Jude ICD and/or Riata Leads that nearly killed Mr. Connelly, a St. Jude representative was physically present at the appointment in Northern California.

B. DEFENDANTS

18. Defendant St. Jude Medical, Inc. is a Minnesota corporation headquartered in St. Paul, Minnesota at One St. Jude Medical Drive. According to the Office of the Minnesota Secretary of State, as of the filing of this Complaint, St. Jude Medical, Inc. remains active and in good standing in Minnesota. At all times alleged herein, St. Jude Medical, Inc. had extensive

contacts in Northern California, including, but not limited to, the presence and participation by St. Jude Medical, Inc. representatives at doctor's appointments with Mr. Connelly in Salinas and Monterey in Monterey County, California.

19. Defendant Abbott Laboratories is an Illinois corporation headquartered in Abbott Park, Illinois at 100 Abbott Park Road. On **January 4, 2017**, Abbott Laboratories announced that it had completed the acquisition of St. Jude Medical, Inc., publicly claiming the company as a leader in the medical device arena. Pursuant to the terms of the Merger Agreement, upon completion of the acquisition, St. Jude Medical became a wholly-owned subsidiary of Abbott. At all times alleged herein, as the successor in interest to St. Jude Medical, Inc., Abbott Laboratories had extensive contacts in Northern California, including, but not limited to, the presence and participation by St. Jude Medical, Inc. representatives at doctor's appointments with Mr. Connelly in Salinas and Monterey in Monterey County, California.

20. Defendant Pacesetter, Inc. dba St. Jude Cardiac Rhythm Management Division ("Pacesetter") is a Delaware corporation with its principal place of business at 15900 Valley View Court, Sylmar, California. On information and belief, Pacesetter, doing business as St. Jude Medical Cardiac Rhythm Management Division, developed, manufactured, and distributed the Riata Leads at issue herein. Pacesetter operated as a wholly owned subsidiary of St. Jude Medical, Inc. and, on information and belief, now operates as a wholly owned subsidiary of Abbott Laboratories.

21. Pacesetter also held the trademark for "Riata." Specifically, on **September 7, 2001**, Pacesetter filed a federal trademark registration. On **November 5, 2002**, the United States Patent and Trademark Office ("USPTO") issued the "Riata" trademark, serial number 76310892, to Pacesetter. The attorney of record listed for "Riata" is Steven M. Mitchell of Pacesetter, Inc., 15900 Valley View Court, Sylmar, CA 91342. The Riata trademark was filed in the category of Medical Instrument Products, and was ultimately cancelled on June 7, 2013.

C. AGENCY, AIDING AND ABETTING, AND CONSPIRACY

22. At all relevant times, each of the Defendants and their directors and officers acted within the scope of their authority and on behalf of each other Defendant. During the relevant

times, Defendants possessed a unity of interest between themselves, and St. Jude Medical exercised control over its subsidiaries and affiliates. As such, each Defendant is individually, as well as jointly and severally, liable to Plaintiff for his damages.

23. At all times relevant to this Complaint, Defendants, and each of them, were acting as the agents, employees, and/or representatives of each other, and were acting within the course and scope of their agency and employment with the full knowledge, consent, permission, authorization, and ratification, either express or implied, of each of the other Defendants in performing the acts alleged in this Complaint.

24. As members of the conspiracies alleged more fully below, each of the Defendants participated and acted with or in furtherance of said conspiracy, or aided or assisted in carrying out the purposes of the conspiracy, and have performed acts and made statements in furtherance of the conspiracy and other violations of California law.

25. Each Defendant acted both individually and in alignment with the other Defendants with full knowledge of their respective wrongful conduct. As such, Defendants conspired together, building upon each other's wrongdoing, in order to accomplish the acts outlined in this Complaint.

26. Defendants are individually sued as principals, participants, aiders and abettors, and co-conspirators in the wrongful conduct complained of and the liability of each arises from the fact that each has engaged in all or part of the improper acts, plans, schemes, conspiracies, or transactions complained of herein.

III. JURISDICTION AND VENUE

27. This Court has diversity jurisdiction over the parties pursuant to 28 U.S.C. § 1332 insofar as the parties are citizens of different states and the amount in controversy in this matter, which numbers in the millions, exceeds Seventy-Five Thousand Dollars ($75,000), exclusive of interest and costs.

28. Venue is proper in this jurisdiction pursuant to 28 U.S.C. § 1391(b)(2) because St. Jude regularly solicited and engaged in business and other persistent courses of conduct and derived substantial revenue from goods used in the State of California and within this district.

Further, the actions and omissions alleged herein occurred, in large part, in Northern California. Representatives of St. Jude were present and participated at Mr. Connelly's doctor's appointments in Salinas and Monterey in Monterey County, California. Further, on November 13, 2016, within fifteen to twenty minutes of Mr. Connelly's arrival at the hospital in Monterey, California, a St. Jude representative, who lived only a few blocks away, arrived at the hospital and used St. Jude machinery to turn off Mr. Connelly's St. Jude ICD and deactivate the Riata Leads. Venue is therefore proper in this jurisdiction.

IV. FACTUAL ALLEGATIONS

A. HISTORY OF IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (ICDS) AND PACEMAKERS

29. In **1980**, the implantable defibrillator was introduced into clinical medicine, and several reports substantiated the ability of the device to terminate ventricular fibrillation automatically. *See* Moss, Arthur J., M.D., *Improved Survival with an Implanted Defibrillator in Patients with Coronary Disease at High Risk for Ventricular Arrhythmia*, N. Engl. J. Med. 1996, 335:1933-1940. Thereafter, several devices were approved and manufactured to detect and treat abnormally fast and irregular heart rhythms and to provide pacing for improper heart rhythms. ICDs include pacemakers and defibrillators. Pacemakers are used to correct slow heart rates. Defibrillators identify and correct both fast and slow heart rates. Using the pacemaker and defibrillator function, an ICD can correct slow heart rates, pace rapid heart rates, and administer a shock to recalibrate the heart and allow for a return to an appropriate rhythm.

30. Leads act to conduct the electrical impulses between the heart and the ICD. Low voltage pacing therapy to treat slow heart rhythms is provided through pace-sense electrodes. High voltage shocks for defibrillation are provided through high voltage conductors. High voltage leads are inserted through a major vessel and attached directly to the muscle on the inside of the heart. Electrodes that sense the heart's rhythm are built into the lead wires and positioned in the heart, where they monitor the heartbeat and transmit an electric shock from the ICD to abort dangerous heart rhythms or pace the heart at a normal rhythm.

31. At all times relevant here, Defendants knew that any failure that compromises the ability of the lead to conduct electrical signals can result in a failure of the ICD to perform properly, potentially resulting in a failure to detect and correct abnormal heart rhythms, or delivery of improper shocks to the heart that can damage or kill the patient. Lead failures include externalization of the conductors, abrasion, fractured wires, insulation loss, loss of ability to capture, changes in electrical characteristics in the ventricle chamber, abnormal lead impedance, sensing failure, and changes in tissue conductor interface.

B. THE REGULATORY APPROVAL PROCESS GENERALLY

32. Premarket approval ("PMA") is the FDA's process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. Due to the level of risk associated with Class III devices, the FDA has determined that general and special controls alone are insufficient to assure the safety and effectiveness of Class III devices. Therefore, these devices require a premarket approval application. A PMA application must be submitted to the FDA for any Class III medical device, including the Riata Lead.

33. The PMA process is a rigorous and time-consuming inquiry into the risks and efficacy of each device. PMA applicants must submit detailed information pertaining to the device, including all studies, reports, and other publications regarding its safety and efficacy, its component parts and functions, and the processes necessary to manufacture and package the device, as well as samples of the device, its labeling, and packaging. 21 U.S.C. § 360e(c)(1); 21 C.F.R. § 814.

C. FDA REGULATORY APPROVAL PROCESS FOR THE RIATA LEADS

34. In **May, 1996**, the FDA approved St. Jude's original Riata Lead application (P950022). From 1996 to 2002, St. Jude submitted and the FDA approved 14 supplements to this original PMA. These supplements altered various aspects of the design and manufacture of the Riata Leads.

35. On **March 11, 2002**, the FDA, pursuant to St. Jude's application No. P950022/S014, approved the Riata Series 1500 Defibrillation Lead System. This approval applied to Riata Model Numbers 1570, 1571, 1580, and 1581.

36. On **January 23, 2003**, the FDA, pursuant to St. Jude's application No. P950022/S015, approved an extension of the shelf-life of the Riata Leads.

37. On **March 25, 2003**, St. Jude added two new models to the Riata Series (Model No. 1572 and 1582), when the FDA approved application No. P950022/S016.

38. On **July 1, 2003**, the FDA, pursuant to St. Jude's application No. P950022/S017, approved the addition of a fluoroscopic marker in the helix tip and the addition of new lead lengths and modifications to the suture sleeve.

39. On **April 12, 2004**, the FDA approved St. Jude's application No. P950022/S018, a modification to the Riata defibrillation lead family to include integrated bipolar leads (Models 1560, 1561, 1562, 1590, 1591, and 1592).

40. In **May 2005**, a series of applications for manufacturing modifications were approved by the FDA. These requests involved "dimensional changes" to the Riata Leads, changes from welding to crimping connectors, changes from manual to automated processes, as well as changes to the order of the manufacturing steps for the crimping process, and changes to the stylet ring and header coupling. *See* application Nos. P950022/S020, P950022/S021, P950022/S022, P950022/S019, and P950022/S023.

41. On **June 3, 2005**, the FDA approved Riata ST Lead Models 7000, 7001, and 7002 under application No. P950022/S024.

42. On **September 13, 2005**, the FDA approved, pursuant to St. Jude's application No. P950022/S026, the removal of a 14-day hold period by instituting total and delta battery current tests.

43. On **November 4, 2005**, the FDA approved, pursuant to St. Jude's application No. P950022/S025, the addition of six lead models with elast-eon 2a lead body insulation materials to the Riata Leads.

44. In **March 2006**, the FDA approved the following changes to the Riata Leads in application Nos. P950022/S027 and P950022/S028.:

a. Modifications to the Riata ST Models 7000, 7001, and 7002 active-fixation defibrillation leads to change the geometric profile of the inner coil and add white pigment to the medical adhesive used for shock coil backfill;

b. Modifications to the Riata ST Models 7000, 7001, and 7002 leads to create an active-fixation integrated bipolar lead. These devices, as modified, were marketed under the trade names Riata ST Models 7010, 7011, and 7012 and were indicated for use with compatible pulse generators; and

c. Modifications to the Riata ST Models 7000, 7001, and 7002 to create a passive fixation and a passive fixation integrated bipolar lead. These devices, as modified, were marketed under the trade names Riata ST Models 7040, 7041, and 7042 (passive fixation) and Riata ST Models 7050, 7051, and 7052 (passive fixation integrated bipolar) and are indicated for use with compatible pulse generators.

45. On **July 7, 2006**, the FDA approved, pursuant to St. Jude's application number P950022/S030, an overlay of the silicone lead body of the Riata ST leads to create the new Riata ST Optim lead models 7020, 7021, 7022, 7030, 7031, 7070, and 7071.

46. In **November 2006**, the FDA approved St. Jude's application No. P950022/S031 to change the supplier for the DR-1 Boot component of its Riata Leads.

47. In **December 2006**, the FDA approved St. Jude's application No. P950022/S032 for a helix attachment modification for the Riata 1580, 1581, and 1582 leads, as well as a crimp-weld coupling modification for the Riata and Riata ST lead families.

48. In **February 2007**, the FDA approved St. Jude's application No. P950022/S033 to add an automated trimming fixture to trim excess silicone adhesive on the shock electrodes during production of the Riata ST family of leads.

49. In **March 2007**, the FDA approved St. Jude's application No. P950022/S034 for the following changes to its Riata Leads:

a. Modification to the crimp slug weld tab;

b. Modification to the distal header assembly;

c. Modification to the PTFE liner in the IS-1 connector leg;

d. Removal of the PTFE liners in the two DF-1 connector legs;

e. Addition of a DF-1 plug accessory to the lead package;

f. Addition of an extra-soft stylet accessory to the lead package;

g. Minor modifications to the User Manual; and

h. Modified radius specification for the spring stopper component.

50. The FDA also approved a change in the supplier of the front seal component (P950022/S035), added an "alternative welding process (P950022/S036), and added alternate vendor of the molded connector boot for the manufacturer of Riata ST Leads (P950022/S037).

51. In **June 2007**, the FDA approved St. Jude's application Nos. P950022/S038, P950022/S039, P960013/S031, and P960013/S032 to change the suppliers of its connector rings and inner crimp sleeve components.

52. In **October 2007**, the FDA approved St. Jude's application No. P950022/S043 for an alternate supplier of ETFE coated cables.

53. In **December 2007**, the FDA approved St. Jude's applications to change the shock coil backfill manufacturing process (P950022/S046), to extend the time between plasma treatment and application of medical adhesive (P950022/S047), and to alternate veil settings during processing of the shock coils (P950022/S048).

54. In **May 2008**, the FDA approved St. Jude's application No. P950022/S045 to transition a manufacturing site to Puerto Rico for Ethylene Oxide sterilization of the pacemakers, ICDs and leads.

55. In **July 2008**, the FDA approved St. Jude's application No. P950022/S051 to transition the manufacturing of the Riata Leads to a plant in Puerto Rico.

D. ST. JUDE CONDUCTS AN INTERNAL AUDIT OF ITS DEFECTIVE RIATA LEADS

56. Cases involving abrasion of Riata Leads date to at least **October 2005**. St. Jude was informed by physicians of several incidents where, as a result of abrasion from the inside-out of the lead wires, St. Jude defibrillators sent unnecessary jolts to the heart or failed to deliver lifesaving shocks to return chaotic heart rhythms back to normal. Despite the fact that several doctors notified St. Jude about Riata Lead malfunctions, St. Jude rebuffed each doctor, telling them that the problems with their respective patients reflected "isolated events." St. Jude knew these were not "isolated events" when it made these statements.

57. As early as at least **2005**, so-called "inside-out abrasion" became a focus of an internal St. Jude audit.

58. In **2008**, St. Jude's inside-out abrasion audit concluded that Riata Leads had potentially serious insulation problems. It is not clear how many cases of inside-out abrasion St. Jude's engineers had identified by 2008, though St. Jude had confirmed 246 cases of any type of insulation breach, including normal wear and tear, according to the inside-out abrasion audit. The inside-out abrasion audit, which had begun looking broadly at insulation problems in 2006, included a special section on inside-out abrasion, which cited examples of inside-out abrasion in at least two devices extracted from patients and also in lab testing. The report, which did not address whether the problems resulted in injuries or deaths, said 32 of the 246 leads examined were damaged enough to inhibit lifesaving shocks. St. Jude had sold more than 120,000 Riata Leads in the U.S. by that time. Given its clear pecuniary interests, despite clear evidence of the unacceptable danger posed by its Riata Leads, St. Jude concluded that the risk of all abrasion-related failures appeared "remote." St. Jude knew this was a false statement when it made it.

E. FDA INSPECTION OF ST. JUDE'S MANUFACTURING FACILITIES AND PROCESSES

59. In **2009**, the FDA conducted a For-Cause Quality Systems Inspection Technique ("QSIT") of the St. Jude and Pacesetter manufacturing facility in Sylmar, California. As part of this inspection, the FDA requested a list of all Corrective and Preventative Action ("CAPA") and Product Improvement Requests ("PIR") opened since 2002. Defendants provided the following PIRs regarding High Voltage Leads:

- 09-005 — Helix extension retraction failure due to the spring popping out of its location and getting jammed between the header coupling and stopper;
- 09-001 — Cable Fracture under Strain Relief Coil DF-1 leg;
- 07-006 — Outer Coil Fractures at IS-1 Connector Ring;
- 06-014 — Hypot Failures in Riata ST Leads Manufacturing;
- 06-012 — Riata Coil Fracture at Inner coil Shaft;
- 06-005 — Missing DF-1 Crimps in HV Lead Manufacturing;
- 06-004 — Swapped DF-1 Labels in HV Lead Manufacturing;
- 06-003 — Riata Lead With Incorrect Conduction Paths;
- 05-016 — Riata Integrated Bipolar IS-1 Connector Dielectric Strength Improvement;
- 05-009 — Riata Lead Abrasion;
- 04-006 — Insufficient Crimp on RV shock coil termination ring employed on the Riata Integrated Bipolar Leads seen in Manufacturing;
- 04-003 — Riata Perforation;
- 03-006 — Riata Lead Cable Coating Abrasion; and
- 02-004 — Riata, Missing Weld, DF-1 Conn. Pin.

60. The FDA inspection revealed that Defendants had deficiencies in the handling of complaints, making Medical Device Reporting ("MDR") determinations, CAPA procedures, and receiving protocols.

61. The inspection further revealed that Defendants failed to follow their procedure for product design developments of the Riata Leads.

62. As a result of these deficiencies, the FDA issued an eight-item FDA-483 Report. An FDA Form 483 Report is issued to firm management at the conclusion of an inspection when investigators have observed any conditions that, in their judgment, may constitute violations of

the Food Drug and Cosmetic Act and related Acts. FDA investigators are trained to ensure that each observation noted on the FDA Form 483 Report is clear, specific and significant.

63. The deficiencies identified by the FDA in **2009** included the following:

a. St. Jude failed to include all information that was reasonably known to the manufacturer on an MDR Report in violation of 21 CFR 803 *et seq*.

b. St. Jude failed to timely submit MDRs to the FDA and such submissions were significantly past the mandatory reporting timeframes without written explanation in violation of 21 CFR 803 *et seq*.

c. St. Jude failed to define the procedures for implementing corrective and preventative actions in violation of 21 CFR 820 *et seq*. Specifically, the Standard Operating Procedure for risk analysis failed to define the methodology for obtaining the Probability of Occurrence that is used in Risk evaluations resulting in inconsistent risk analyses.

d. St. Jude failed to review its sampling methods for adequacy of their intended use in violation of 21 CFR 820 *et seq*. Specifically, the procedure "Receiving Inspection Sampling Program" allowed components to be accepted without receiving inspections and review of vendor certificates (Dock to Stock method). The procedure did not have a monitoring program for receiving components that were subject to Dock to Stock methods. As of June 23, 2009, a significant number of critical components for defibrillation leads were Dock to Stock components. In addition, the sections of Dock to Stock General Requirements and Dock to Stock Part Declassification were purged without written justifications.

e. St. Jude failed to perform design reviews at appropriate times in violation of 21 CFR 820 *et seq*. Specifically, Design Phase reviews were not conducted as required by the procedure for Global Product Development Protocol and the Product Development Plan. Additionally, team meeting minutes were not maintained as required.

f. St. Jude failed to perform a complete risk analysis in violation of 21 CFR 820 *et seq*. Specifically, the Failure Mode, Effects, and Criticality Analysis (FMECA) did not include all drawings and St. Jude was unable to explain why component drawings were not evaluated for failure mode, effect, and criticality analysis. The design FMECA analysis for components and top assembly drawings were part of the risk analysis for the Riata Leads.

g. St. Jude failed to establish procedures for the validation or verification review, and approval of design changes before their implementation in violation of 21 CFR 820 *et seq*. Specifically, St. Jude had no written procedure describing the review and approval process of the design verification plan and report, when design changes require a verification plan.

h. St. Jude failed to resolve discrepancies noted at the completion of design verification in violation of 21 CFR 820 *et seq*. Specifically, the review of Quality Test Report ("QTR") 1403 for Riata Series 1500 shows someone who reviewed the data sheets had made a change to the specification of DC resistance on the Qualification Test Data Sheets for Composite Lead Tensile Test, but the reason for the discrepancy and reason for the change were not discussed in the QTR or meeting minutes.

64. On **October 17, 2012**, the FDA conducted a subsequent 483 inspection of Defendants' Sylmar, California manufacturing facility and identified several deficiencies including failures regarding design verification, complaint handling, CAPA procedures, risk analyses, inspection/measuring/testing/calibration of equipment, document control, and employee training.

F. MANUFACTURING DEFECTS OF THE RIATA LEADS

65. From **2002-2010**, St. Jude applied for over 27 manufacturing or process changes to the Riata Leads. The FDA approved these changes in a PMA and multiple supplements. Upon information and belief, Defendants failed to manufacture the Riata Leads consistent with the design specifications and/or the approved changes, thereby creating a defective product.

66. Upon information and belief, one of these defects includes inconsistent insulation diameters surrounding the electric conductors. Insulation diameters are required by the design specifications, PMA, and/or federal requirements to be consistent. Upon information and belief, Defendants failed to manufacture uniform insulation diameters leading to an increased risk of abrasion at thinner insulation sites, as well as externalization, which leads to an increased risk of device failure.

67. The breach of insulation and externalization of the lead wires on the Riata Leads can cause Riata Leads to short and to transmit incorrect information or noise to the defibrillator. This, in turn, can cause the defibrillator to produce unnecessary and very painful shocks of electricity. Alternatively, the breach of insulation and externalization of the lead wires can cause a failure of proper communication between the leads and the defibrillator, at which point the life-saving therapies of the device are unavailable.

68. Further, upon information and belief, Defendants inconsistently applied a lubricious interface between the inner and outer insulation in violation of the design specifications and/or PMA. Upon information and belief, this inconsistent application may have led to increased friction within the lead body, promoting abrasion and/or externalization.

69. Additionally, Defendants applied for and received approval for multiple changes to the cure and sterilization processes used in the manufacture of the Riata Leads. Upon information and belief, Defendants failed to comply with the approved methods and/or specifications of curing and sterilization during the manufacture of the Riata Leads. Upon information and belief, Defendants failed to follow the approved cure and sterilization processes, resulting in reduced tensile strength of the silicone insulation.

70. Finally, Defendants applied and received approval for numerous modifications to the welding and crimping procedures in the manufacture of the Riata Leads. Upon information and belief, a controlled, uniform degree of force is required when applying the crimp. Upon information and belief, Defendants failed to crimp with a controlled, uniform, degree of force, resulting in insecure crimps over the length of the Riata Leads.

71. Failure of the Riata Leads was apparently unrelated to patient age or sex, ICD indication, the primary heart disease, left ventricular ejection fraction, or lead tip position, suggesting that manufacturing problems are responsible for the failure of the devices.

G. RECALL OF THE RIATA LEADS

72. On **December 15, 2010**, St. Jude published a "Dear Doctor" letter regarding its Riata Leads. In the 2010 letter, St. Jude indicated that issues with defects in the insulation had been identified in Riata Lead Models 1560, 1561, 1562, 1570, 1571, 1572, 1580, 1581, 1582, 1590, 1591, 1592, 7000, 7001, 7002, 7010, 7011, 7040, 7041, and 7042.

73. After years of knowing about defects in its Riata Leads, St. Jude finally admitted that "the Riata and Riata ST Family of Silicone Leads have exhibited an insulation abrasion rate of 0.47% over nine years of use." St. Jude further admitted that the silicone used on these leads was "vulnerable to abrasion."

74. In the **2010** Dear Doctor letter, despite years of knowing about Riata Lead defects, including defects associated with insulation abrasion, Defendants finally admitted publicly that Riata Lead insulation abrasion had been associated with:

a. Oversensing (leading to inhibition of pacing or inappropriate high voltage therapy);

b. Undersensing;

c. Loss of capture;

d. Changes in pacing and/or high voltage lead impedances; and

e. Inability to deliver high voltage therapy.

75. Incredibly, despite the dangers associated with the Riata Leads, St. Jude did not initiate a voluntary recall of the leads at that time. Rather, St. Jude simply noted that it was "phasing-out" all Riata Lead models by the end of 2010.

76. On **November 28, 2011**, St. Jude published a second Dear Doctor letter relating to the same set of Riata Lead Models as the 2010 Dear Doctor letter. The November 28, 2011 Letter updated the previously published failure rates for the Riata Leads, indicating that it had increased to 0.63% from its 2010 rate of 0.47%. Again, despite the dangers associated with these leads, St. Jude did not initiate a voluntary recall.

77. On **December 21, 2011**, the FDA reclassified St. Jude's Dear Doctor advisories to a Class I Recall.

78. A Class I Recall is the most serious level of recall and is defined as a situation in which there is a reasonable probability that the use of or exposure to a product will cause serious adverse health consequences or death. The FDA indicated that the reason for the recall was that "failures associated with lead insulation abrasion on the St. Jude Riata and Riata ST Silicone Endocardial Defibrillation Leads may cause the conductors to become externalized. If this occurs, this product may cause serious adverse health consequences, including death."

H. PHYSICIANS EXPOSE THE RIATA LEAD DEFECTS

79. Beginning in **September 2011**, Dr. Robert G. Hauser of the Minneapolis Heart Institute Foundation ("MHI"), began researching the FDA's MAUDE database for reported

deaths related to the St. Jude Riata Leads. The MAUDE database is a voluntary reporting system maintained by the FDA. The majority of reports are filed by manufacturers, who are required by law to report device-related adverse events.

80. In a report sent to the Heart Rhythm Journal in **March 2012**, Dr. Hauser detailed his research and conclusions comparing the failure rates of the St. Jude Riata Leads to the reported failure rates of a competitor's leads. Hauser, M.D., *et al*., *Deaths Caused by the Failure of Riata and Riata ST Implantable Cardioverter-Defibrillator Leads*, Heart Rhythm Society, 2012 Aug, 9(8):1227-35. In his report, Dr. Hauser indicated that the reports showed that 31% of the deaths involving the Riata Leads were lead-related, whereas 8% of the deaths involving the competitor's lead were found to be lead-related. *Id.* It is important to note that adverse events are often under-reported. *Id.* Additionally, Dr. Hauser noted: "Abnormal high voltage impedances were the hallmark of catastrophic Riata and Riata ST lead failure, often resulting in failure to defibrillate." *Id.* Finally, Dr. Hauser concluded that the Riata Leads are prone to high-voltage failures that have resulted in multiple deaths. *Id.*

81. On **March 8, 2012**, Dr. Hauser's article entitled "Here We Go Again – Another Failure in Postmarketing Device Surveillance" was published in the New England Journal of Medicine. This article exposed the increased harm in failing to have an accurate, active post-market reporting mechanism for medical devices and advocated for greater research and review of medical device failures in order to better protect patients. *See* Hauser, M.D., *Here We Go Again — Another Failure in Postmarketing Device Surveillance*, 366 New. Eng. J. Med. 873, 873-75 (2012). St. Jude Medical reacted to Dr. Hauser's article in what industry analysts have described as a "rare," "unprecedented," and "confounding" manner by demanding that the New England Journal of Medicine retract Dr. Hauser's article. *See* Barry Meier and Katie Thomas, *At St. Jude, Firing Back at Critics*, N.Y. TIMES, Apr. 11, 2012, at Bl; Susan Kelly and Debra Sherman, *Analysis: Heart device troubles cloud St. Jude's outlook*, Reuters.com, Apr. 13, 2012, http://www.reuters.com/article/us-stjude-idUSBRE83C0ME20120413.

82. In **May 2012**, Dr. Hauser published additional findings regarding the Riata Lead insulation defects. *See* Houser, M.D., *et al*., *Riata Implantable Cardioverter-Defibrillator Lead*

Failure: Analysis of Explanted Leads with a Unique Insulation Defect, 9 Heart Rhythm J. 742 (2012).

83. In **2012**, the FDA ordered Defendants to collect clinical data related to the potential for premature insulation failure in Riata and Riata ST Leads. The FDA required Defendants to conduct three-year post-market surveillance studies, or Section 522 studies, to address concerns related to premature insulation failure and to address important questions related to follow-up of affected patients.

84. In **January 2013**, a study published in the Heart Rhythm Journal indicated that Defendants had recently advised that the rate of cable externalization was higher than previously reported. The article also stated a number of studies have confirmed that Riata Leads fail more often than other brands.

85. When problems with the Riata Leads were first reported, most attention focused on the unusual pattern of "inside out abrasion," which led to externalized conductors visible on fluoroscopy in 10-25% of patients. However, the Riata Lead is also prone to other types of failure in the high-voltage circuit. Since these problems may become apparent only when the high-voltage circuit is activated, they are potentially much more dangerous. As such, in patients who are relatively healthy and young, early extraction and replacement of at least one of the defective Riata Leads – the one that delivers the shock – is the surest way to safeguard the patient's health. At a minimum, patients should be given this option.

86. According to Dr. Melanie Maytin from Brigham and Women's Hospital in Boston, Massachusetts, "Patients should be told that there is a true failure rate (both structural and electrical). Patients should be offered the opportunity to discuss all potential management strategies, from extraction to abandonment to observation, with physicians expert in lead extraction." Boggs, M.D., *Riata ICD Lead Removal Challenging but Safe*, Reuters Health Medical News, June 5, 2014. However, due to the monetary costs of extraction and replacement, St. Jude failed to recommend that certain categories of patients undergo an extraction or replacement procedure or at least be given the option, despite the fact that extraction of the Riata

Leads can be performed safely by experienced operators at high-volume centers with a complication rate comparable to published data. *Id.*

I. MR. CONNELLY HAS ST. JUDE ICD AND RIATA LEADS SURGICALLY INSTALLED

87. In **2002** in Salinas, California, Mr. Connelly met with a cardiologist at Salinas Valley Memorial Hospital. Based on Mr. Connelly's reports of shortness of breath and a family history of heart attacks – his father passed away after a heart attack at the age of 46 – the cardiologist ordered an echocardiogram. Based on the results of the echocardiogram, the cardiologist advised Mr. Connelly that he should undergo surgery to install an ICD. Before agreeing to do so, Mr. Connelly obtained a second opinion from another cardiologist, a specialist in pacemaker and ICD implants at the Community Hospital of Monterey Peninsula in Monterey, California. The specialist agreed that Mr. Connelly should have an ICD implant and leads installed to monitor his heart and to save him in the event of a heart attack.

88. On **May 5, 2003** in Salinas, California, based on the advice of these two cardiologists, Mr. Connelly underwent surgery at Salinas Valley Memorial Hospital to install a St. Jude ICD and St. Jude Leads. Specifically, the ICD implant specialist installed a St. Jude Medical EPIC DR, Model V-235, Serial No. 19538. The surgeon installed St. Jude Riata Leads. Thereafter, following his doctor's orders, Mr. Connelly attended biannual checkups to monitor his heart and the St. Jude ICD and Riata Leads. At each of these checkups, which took place in either Monterey or Salinas, California, in addition to a doctor or hospital employee, a St. Jude representative was always present to administer the checkup of the St. Jude ICD and Riata Leads. At no time did the St. Jude representative inform Mr. Connelly that there had been any problems with either the St. Jude ICD or the Riata Leads. At no time did the St. Jude representative or anyone from St. Jude advise Mr. Connelly or, on information and belief, Mr. Connelly's doctors or the FDA, that patients like Mr. Connelly should be given the option to extract and or extract and replace the defective Riata Leads.

89. In **2007** in Monterey, California, Mr. Connelly's cardiologist informed him that the battery life of his St. Jude ICD was down to approximately 40%. On this basis, the cardiologist advised Mr. Connelly to undergo a second surgery to swap in a new St. Jude ICD. Given the lack

of any warning from St. Jude regarding defects in the Riata Leads installed in Mr. Connelly, the cardiologist recommend that Mr. Connelly retain the original Riata Leads and connect them to a new ICD.

90. On **November 13, 2007** in Monterey, California, based on the advice of his cardiologist, Mr. Connelly underwent surgery at the Community Hospital of Monterey Peninsula to install a new St. Jude ICD. Specifically, the ICD implant specialist installed a St. Jude ICD, Model V-268, Serial No. 393021. Thereafter, following his doctor's orders, Mr. Connelly attended biannual checkups to monitor his heart and the St. Jude ICD and Riata Leads. As before, at each of these checkups, which took place in either Monterey or Salinas, California, in addition to a doctor or hospital employee, a St. Jude representative was always present to administer the checkup of the St. Jude ICD and Riata Leads. At no time did the St. Jude representative inform Mr. Connelly that there had been any problems with either the St. Jude ICD or the Riata Leads. At no time did the St. Jude representative or anyone from St. Jude advise Mr. Connelly or, on information and belief, Mr. Connelly's doctors or the FDA, that patients like Mr. Connelly should be given the option to extract and or extract and replace the defective Riata Leads.

91. In **2015**, based on the advice of his cardiologist, Mr. Connelly again underwent surgery at Salinas Valley Memorial Hospital to install a third St. Jude ICD because the battery of the second ICD had diminished to unacceptable levels. Given the lack of any warning from St. Jude regarding defects in the Riata Leads installed in Mr. Connelly that counseled in favor of replacing them, the cardiologist recommend that Mr. Connelly retain the original Riata Leads and connect them to the new, third ICD. Thereafter, following his doctor's orders, Mr. Connelly attended checkups to monitor his heart and the St. Jude ICD and Riata Leads. As before, at each of these checkups, which took place in either Monterey or Salinas, California, in addition to a doctor or hospital employee, a St. Jude representative was always present to administer the checkup of the St. Jude ICD and Riata Leads. At no time did the St. Jude representative inform Mr. Connelly that there had been any problems with either the St. Jude ICD or the Riata Leads. At no time did the St. Jude representative or anyone from St. Jude advise Mr. Connelly or, on

information and belief, Mr. Connelly's doctors or the FDA, that patients like Mr. Connelly should be given the option to extract and or extract and replace the defective Riata Leads.

J. THE DEFECTIVE ST. JUDE ICD AND RIATA LEADS MALFUNCTION, TRIGGERING 16-20 VIOLENT SHOCKS THAT IRREPARABLY HARMED PLAINTIFF CONNELLY

92. On **November 13, 2016**, alone at his home in Carmel, California, between five and six in the morning, Mr. Connelly was violently awakened when the St. Jude ICD and/or Riata Lead malfunctioned and shocked Mr. Connelly. Mr. Connelly struggled to get out of bed to reach the telephone to call 911; he was terrified that he was having a deadly heart attack. As he shuffled to the telephone in agonizing pain and during the 911 call, the St. Jude ICD and Riata Leads shocked Mr. Connelly again and again, causing excruciating pain. Mr. Connelly believed he was dying. The intensity of the shocks was so powerful, Mr. Connelly doubled over and was ultimately knocked to the ground. He crawled to the front door and managed to move out to the porch. When the ambulance arrived in what seemed like an eternity later, Mr. Connelly was found in the fetal position on his front porch. In total, Mr. Connelly was shocked an estimated sixteen to twenty times, causing irreparable harm to his heart, body, and mind.

93. Mr. Connelly was rushed to the Community Hospital of Monterey Peninsula. Within fifteen to twenty minutes of Mr. Connelly's arrival at the hospital, a St. Jude representative, who lived only a few blocks away, arrived and used St. Jude machinery to turn off Mr. Connelly's St. Jude ICD and deactivate the Riata Leads.

94. While Mr. Connelly was still in anguish, the St. Jude representative quipped: "it looks like you hit the lottery on this one." Mr. Connelly was hospitalized for five days and released with a Zoll Life Vest, an external defibrillator.

95. On **March 2, 2017**, in Palo Alto, California, based on the advice of his cardiologist, Mr. Connelly underwent surgery at the Veterans Affairs (VA) Hospital to install a fourth St. Jude ICD and to replace the faulty Riata Lead.

96. As a direct result of the defective and malfunctioning St. Jude ICD and/or Riata Leads, Mr. Connelly suffered incredible physical pain and continues to suffer mental and physical anguish. For example, Mr. Connelly has trouble sleeping and has to see a psychologist for his

Post Traumatic Stress Disorder. In addition, Mr. Connelly was forced to miss work and spend money on medical costs arising from St. Jude's defective ICD and/or Riata Leads.

V. CLAIMS FOR RELIEF

COUNT ONE

STRICT LIABILITY — MANUFACTURING DEFECT

97. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

98. Defendants manufactured, distributed, and sold Riata Leads.

99. Upon information and belief, the Riata Leads, including Plaintiff Connelly's Riata Leads, possess a manufacturing defect because the actual manufacture of the Riata Leads differs from the specifications set forth in the PMA and the conditions for approval.

100. This manufacturing defect renders the Riata Leads unreasonably dangerous for their intended use and Plaintiff Connelly could not have anticipated the danger the defect in this product created. This manufacturing defect was present in the Riata Leads when they left Defendants' control. The Riata Leads were expected to and did reach Plaintiff Connelly without substantial change or adjustment to their mechanical function upon implanting the Riata Leads.

101. As a direct and proximate result of the manufacturing defects, Plaintiff suffered and will continue to suffer severe physical injuries and/or death, permanent disability, severe emotional distress, mental anguish, economic losses and other damages. Defects in Defendants' Riata Leads were a substantial factor in causing Plaintiff's harm.

102. The aforementioned acts of Defendants were willful, oppressive, and/or malicious. Plaintiff is therefore entitled to punitive damages in an amount to be proven at trial, in addition to all other damages and other relief. Adequate punitive damages are particularly warranted in this case to ensure some measure to deter similar future conduct by Defendants, and each of them. Given the cost of replacing all defective Riata Leads in patients like Mr. Connelly, St. Jude chose money over patient safety, even though St. Jude knew there was a real risk of catastrophic damage and death to patients with St. Jude Riata Leads, including Mr. Connelly. Punitive damages are therefore appropriate in this case.

103. WHEREFORE, Plaintiff prays for relief as set forth below.

COUNT TWO

STRICT LIABILITY — FAILURE TO WARN

104. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

105. Defendants manufactured, distributed, and sold Riata Leads.

106. The Riata Leads had potential risks that were known and knowable to Defendants in light of direct reports by physicians to Defendants, internal audits at Defendants, and the scientific and medical knowledge that was generally accepted in the scientific and medical community at the time of Defendants' manufacture, distribution, and sale of the Riata Leads.

107. The potential risks of the Riata Leads presented a substantial danger when the product is used in an intended or reasonably foreseeable way.

108. Ordinary consumers, including Plaintiff Connelly, would not have recognized the potential risks posed by the Riata Leads.

109. Defendants had and continue to have a duty to provide ongoing warnings and instructions regarding safety hazards associated with the Riata Leads.

110. Defendants breached this duty by failing to provide timely and complete reports regarding known and knowable safety hazards and/or potential defects associated with the Riata Leads as well as appropriate remedial steps to safeguard patient health and avoid serious harm to patients, including Plaintiff Richard Connelly.

111. Defendants also breached this duty by failing to conduct adequate risk analyses and investigations required by federal regulations regarding safety hazards and/or potential defects associated with the Riata Leads. Defendants' failure to warn and investigate rendered the Riata Leads unreasonably and dangerously defective beyond the extent contemplated by ordinary patients with ordinary knowledge regarding the Riata Leads.

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112. Had Defendants not breached their duty to warn, relevant information relating to the safety and efficacy of the Riata Leads would have reached Plaintiff's doctors, and would have caused Plaintiff to extract the device, prior to Plaintiff suffering the repeated, violent electrical shocks, as alleged above.

113. As a direct and proximate result of Defendants' failure to warn, Plaintiff suffered and will continue to suffer severe physical injuries and/or death, permanent disability, severe emotional distress, mental anguish, economic losses and other damages.

114. The aforementioned acts of Defendants were willful, oppressive, and/or malicious. Plaintiff is therefore entitled to punitive damages in an amount to be proven at trial, in addition to all other damages and other relief. Adequate punitive damages are particularly warranted in this case to ensure some measure to deter similar future conduct by Defendants, and each of them. Given the cost of replacing all defective Riata Leads in patients like Mr. Connelly, St. Jude chose financial rewards over patient safety, even though St. Jude knew there was a real risk of catastrophic damage and death to patients with St. Jude Riata Leads, including Mr. Connelly. Punitive damages are therefore appropriate in this case.

115. WHEREFORE, Plaintiff prays for relief as set forth below.

COUNT THREE

NEGLIGENCE PER SE

116. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

117. Federal Regulations impose standards of care on Defendants related to the manufacture, marketing, and sale of the Riata Leads.

118. Plaintiff alleges the Federal Regulations define the standard of care, and thus, St. Jude's duties are contained in, but not limited to, the following: 21 CFR 803.10; 21 CFR 803.50; 21 CFR 803.52; 21 CFR 803.53; 21 CFR 803.56; 21 CFR 806; 21 CFR 814.1; 21 CFR 814.3; 21 CFR 814.9; 21 CFR 814.20; 21 CFR 814.37; 21 CFR 814.39; 21 CFR 814.80; 21 CFR 814.82; 21 CFR 814.84; 21 CFR 820.5; 21 CFR 820.20; 21 CFR 820.22; 21 CFR 820.25; 21 CFR 820.70.

119. Plaintiff Connelly is within the class of persons the statutes and regulations protect and Plaintiff's injuries are the type of harm these statutes and regulations are meant to prevent.

120. Upon information and belief, the Conditions of Approval for the Riata Leads incorporate these statutes and regulations. Failure to comply with the Conditions of Approval invalidates the approval order. *See* 21 CFR 814.82(c). Defendants failed to comply with the Conditions of Approval and Federal Regulations.

121. As a direct and proximate result of Defendants' failure to comply with the PMA and conditions of approval for manufacturing the Riata Leads, Plaintiff suffered and will continue to suffer severe physical injuries and/or death, permanent disability, severe emotional distress, mental anguish, economic losses and other damages.

122. The aforementioned acts of Defendants were willful, oppressive, and/or malicious. Plaintiff is therefore entitled to punitive damages in an amount to be proven at trial, in addition to all other damages and other relief. Adequate punitive damages are particularly warranted in this case to ensure some measure to deter similar future conduct by Defendants, and each of them. Given the cost of replacing all defective Riata Leads in patients like Mr. Connelly, St. Jude chose financial rewards over patient safety, even though St. Jude knew there was a real risk of catastrophic damage and death to patients with St. Jude Riata Leads, including Mr. Connelly. Punitive damages are therefore appropriate in this case.

123. WHEREFORE, Plaintiff prays for relief as set forth below.

COUNT FOUR

NEGLIGENCE

124. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

125. Defendants were negligent in the manufacture, distribution, sale, and in person monitoring and follow-up with patients installed with Riata Leads, including Plaintiff Richard Connelly.

126. Defendants have a duty to manufacture the Riata Leads consistent with the PMA and conditions of approval. Likewise, Defendants had a duty to use, at a minimum, reasonable care in the distribution, sale, and in person monitoring and follow-up with patients installed with Riata Leads, including Plaintiff Richard Connelly. Defendants breached this duty.

127. As a direct and proximate result of Defendants' negligent manufacturing, distribution, sale, and in person monitoring and follow-up of the Riata Leads, Plaintiff Connelly suffered and will continue to suffer severe physical injuries and/or death, permanent disability, severe emotional distress, mental anguish, economic losses and other damages.

128. Defendants' negligence was a substantial factor in causing Mr. Connelly's harm.

129. The aforementioned acts of Defendants were willful, oppressive, and/or malicious. Plaintiff is therefore entitled to punitive damages in an amount to be proven at trial, in addition to all other damages and other relief. Adequate punitive damages are particularly warranted in this case to ensure some measure to deter similar future conduct by Defendants, and each of them. Given the cost of replacing all defective Riata Leads in patients like Mr. Connelly, St. Jude chose financial rewards over patient safety, even though St. Jude knew there was a real risk of catastrophic damage and death to patients with St. Jude Riata Leads, including Mr. Connelly. Punitive damages are therefore appropriate in this case.

130. WHEREFORE, Plaintiff prays for relief as set forth below.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendants as follows:

A. For compensatory and general damages according to proof;

B. For past and future medical expenses and incidental expenses according to proof;

C. For past and future loss of earnings and earning capacity according to proof;

D. For pre- and post-judgment interest on all damages as allowed by law;

E. For an award of attorneys' fees and costs;

F. For punitive damages in an amount according to proof;

G. For costs of suit incurred herein; and

H. For such other and further relief as this Court may deem just and proper.

Dated: April 10, 2017

COTCHETT, PITRE & McCARTHY, LLP

CAMILO ARTIGA-PURCELL
Attorneys for Plaintiff

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury as to all claims in this action.

Dated: April 10, 2017

COTCHETT, PITRE & McCARTHY, LLP

CAMILO ARTIGA-PURCELL
Attorneys for Plaintiff